

California Drug Recall Information



Recall Name

Sagent Pharmaceuticals Recalls Atracurium Besylate Injection Due to Potential Product Sterility Concerns

Recall Date	Product Description	Recalling Firm	Recall Reason
2/23/15	 Atracurium Besylate Injection, USP 50mg/5mL single-dose vials	Sagent Pharmaceuticals, Inc. Schaumburg, IL [manufactured by: Emcure Pharmaceuticals Ltd.]	Due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.
Recall Class	Product Identification	Distribution	Affected Dates
N/A	Suspect Lots Recalled: • 50mg/5mL vials VATA012 VATA015 • 100mg/10mL vials VATB012 VATB013 VATB014 VATB017	CA , nationwide	Distributed: February 2014 through February 2015

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/Safety/Recalls/ucm435336.htm